

MAI MEDICAL
ACCESSORIES,
INCORPORATED

92 Youngs Road
Trenton, New Jersey 08619
(609) 890-8304
FAX (609) 890-0638

2283 '98 MAR -9 P1:42

March 4, 1998

Dockets Management Branch (HFA-305)
FDA
12420 Parklawn Drive
Rockville, MD 20857

Dear FDA,

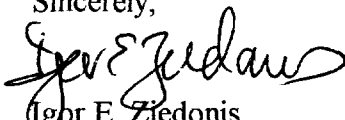
I am glad you are considering regulating the reconditioners, refurbishers of medical equipment. This market is in need of full GMP compliance. My company manufactures products under FDA GMP and is inspected every two years. I think you would be doing the right thing in protecting the public if you would inspect the medical remarketer industry.

The medical service market is full of companies repairing equipment with used, bogus parts. And, these companies have no problem hiding the fact they use used parts. Of course, I'd be the first to tell you some hospital biomedical departments don't care about receiving used parts in their repairs. All they want is price, price, price. That's fine if the equipment was going to be used on them, but unfortunately it's the unknowing patients who are being diagnosed with this bogus equipment that might become the victims.

And, it's not only repairing equipment with used parts. How about selling used products as brand new or mislabeling equipment they're sending out to hospitals. Why repair equipment with new parts if no one is regulating them and they can get away with using used parts in repairs. There's so much profit in selling used parts and the public has no idea what is being used on them to fix their ailments. The government wants to regulate tobacco, they better also look at this market.

I have enclosed past correspondence to the FDA to highlight some, but far from all the abuses in this business. If you would like to discuss this further, or personally inspect some of the best of the worst junk sent to hospitals by remarketing companies, please contact me at your earliest convenience.

Sincerely,


Igor E. Ziedonis
President

97N-0477

C-26

MAI MEDICAL
ACCESSORIES.
INCORPORATED

92 Youngs Road
Trenton, New Jersey 08619

(609) 890-8304
FAX (609) 890-0638

April 10, 1996

COPY

Mr. John F. Stigi
Director
Div. of Small Manufacturers
Office of Health and Industry Programs
Food and Drug Administration
Rockville, MD 20857

Dear Mr. Stigi,

Thank you for your notice regarding the Medical Device Industry Initiatives. It clearly looks as if these new changes will be very positive.

As I am not sure who I need to contact, I would ask you to forward the following information to the proper compliance officer.

Medical Accessories, Inc. has been registered and inspected by the FDA since 1976. I can find no proof of two of our competitors being registered anywhere. The problem with this is two fold. First, our costs are higher due to compliance which we wholeheartedly endorse. Second, they are using used parts in their repair service, one of them advertised that they sell new parts only for us to discover that half the parts were used and they mislabel their products. All very serious issues which could adversely impact hospital patients. I have proof on all of the above. Further, an inspection would reveal they use used parts because they would be unable to show you brand new replacement parts for ultrasonic transducers and tocotransducers.

The companies I am specifically naming are:

- | | |
|--------------------------------|------------------------------------|
| 1.) Medical Cables, Inc. (MCI) | 2.) SMC (is run by MCI's daughter) |
| 1340 Logan Ave. | 800 336-5268 |
| Costa Mesa, CA 92626 | she doesn't advertise her address |

As an example, I have enclosed a label error from MCI. The error on this label is that you cannot use a 111 or 112 ultrasonic transducer with a 115 fetal monitor. Each transducer has an entirely different connector and they cannot be interchanged between fetal monitors. In fact, a 111 transducer cannot be used with either a 112 or 115 fetal monitor. It has a circuit in it that the 112 and 115 don't. This is a very serious defect in labeling.

I am also glad to hear the FDA may begin regulating the used equipment market. This area is filled with so many cheats, unethical

Specializing in Fetal Monitoring Products

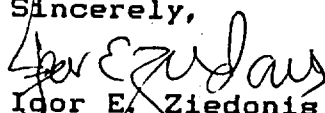
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(609) 890-8304
FAX (609) 890-0638

Mr. John F. Stigi
April 10, 1996
Page 2

dealers that without question, hospitals and patients are being
lied to and cheated. We encourage your review of this as we have been in
compliance since 1976 and we also endorse the FDA's effort to protect the
patient, hospital and endusers.

Sincerely,


Igor E. Ziedonis
President

MEDICAL ACCESSORIES INCORPORATED

92 YOUNGS ROAD
TRENTON, NJ 08619

IGOR ZIEDONIS
PRESIDENT
(609) 890-8304
FAX: (609) 890-0638



Phaco Ultrasonic Handpieces

Alcon / CooperVision Models 10,000 & 9001

Chiron, Storz

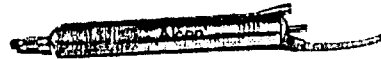
Repair.....	\$ 495.00
Refurbish	\$1,595.00
Repair/ Exchange	\$1,895.00
Refurbished Handpieces Available...	\$2,295.00

AMO (Allergan) Handpieces

New / Exchange.....	\$1,895.00
Refurbish.....	\$ 1,295.00

Avit Handpieces

New / Exchange.....	\$ 750.00
Repair.....	\$ 495.00



30 Day Warranty On Repairs 48 Hr. Turnaround
3 Month Warranty On Refurbished Handpieces
MCI Buys & Sells New & Used Phaco & Microscope Equipment

Medical Cables, Inc.
1340 Logan Avenue
Costa Mesa, CA 92626

Call Today
For Complete Catalog
SE HABLA ESPANOL

(800) 828-1599
FAX (714) 545-7212

READER SERVICE NO. 38

SEPTEMBER/OCTOBER 1995

37

See enclosed, I'd make sure
They prove They use only brand
new parts in This. See enclosed,
They previously sold "new"
transducers. That had used parts
in them.

IL

THE BEST SOURCE FOR CABLES IS MCI

Specializing in Repair for COROMETRICS and
HEWLETT-PACKARD Fetal Monitoring Accessories

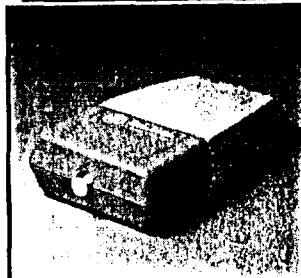
New Ultrasound Transducers \$315.00
Compatible With COROMETRICS Model 111,112,115

REPAIR / CALIBRATION

COROMETRICS TOCO TRANSDUCER	Model 111,112,115	\$165.00
COROMETRICS ULTRASOUND	Model 111,112,115	\$195.00
HEWLETT-PACKARD ULTRASOUND	Model 8030,8040	\$195.00
HEWLETT-PACKARD TOCO TRANSDUCER	Model 8030,8040	\$205.00
HEWLETT-PACKARD "QUARTZ" PRESSURE TRANSDUCER	Model 1290A	\$275.00

ECG - TELEMETRY

REPAIR ♦ CALIBRATION/PM



SPACE LABS	\$325.00 / \$195.00
HEWLETT-PACKARD	\$350.00 / \$225.00
OTHER MANUFACTURERS	-Call For Prices-
All Parts & Labor Included PM Includes Alignment, Calibration, and Cleaning	

Number One in Customer Satisfaction

COMPARE OUR SERVICE

- ♦ Fast Turnaround Time (most repairs 48 hours)
- ♦ We Use Only Original Manufacturer Parts
- ♦ All Units Shipped Next Day Air
- ♦ 6 Month Warranty

MCI MEDICAL
CABLES
INCORPORATED

1308 Logan Ave. Suite F
Costa Mesa, CA. 92626

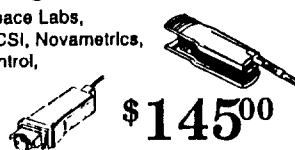

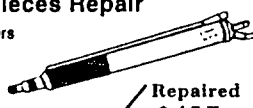


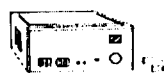
714-545-3469

FAX 714-545-7212

We bought
one through
a friend
and found
it to
contain 50%
used parts.
I still
have this
transducer

42

On-Time & Expert Repairs

<p>Pulse Oximeter Pre-Amp or Finger Probe Repair</p> <p>Nellcor, Space Labs, Ohmeda, CSI, Novametrics, Physio-Control, Datascope</p>  <p>\$145⁰⁰</p>	<p>New! Pulse Oximeter Monitors</p> <p>CSI, Criticare System 504, 503, 503 SPO₂T</p> <p>STARTING AT \$750⁰⁰</p> 	<p>Alcon Phaco Ultrasonic Handpieces Repair</p> <p>Includes Model Numbers 10000 & 9001 We Also Repair Ste, Amo, Storz & Chiron Handpieces- Call for Estimate</p> <p>Refurbished \$1,595</p> <p>Repaired \$495</p> 
<p>Fetal Monitoring Transducer Cable Repair</p> <p>Corometrics, Hewlett Packard, Litton</p>  <p>\$165^{00*}</p>	<p>Holter Patient Cables & Lead Sets</p> <p>NEW ITEMS!!</p> <ul style="list-style-type: none"> • ACS • A.I.R. • Del Mar • Zymed • Rozinn • SpaceLabs <p>STARTING AT \$17⁰⁰</p> 	<p>HP Telemetry, Transmitter & Receiver SPECIAL!!</p> <p>Hewlett-Packard Telemetry, Transmitter & Receiver Series 78100/ 78101</p> <p>FOR SALE \$750⁰⁰ PER SET</p> 

Most Repairs 48 Hr. Turnaround • VOLUME DISCOUNTS AVAILABLE!!
 *PRICE INCLUDES ALL PARTS & LABOR (IF REPAIRABLE)
 6 Month Warranty on Cables • 30 Day Warranty On Phaco Ultrasonic Repairs
 90 Day Warranty On Refurbished Phaco Ultrasonic Handpieces

CALL TODAY FOR COMPLETE CATALOG OF PATIENT CABLES

SMC

(800) 336-5268

MAI MEDICAL
ACCESSORIES
INCORPORATED

800 243 3952

92 Youngs Road • Trenton, NJ 08619 • (609) 890-8304

April 10, 1990

→ 84T 545

Mr. Pat Dwyer
Marketing Manager
Corometrics Medical Systems, Inc.
61 Barnes Park Rd. N.
Wallingford, CT 06492

COPY

SENT VIA FAX TRANSMISSION

Dear Pat,

It was a pleasure speaking with you earlier. I am faxing you copies of the invoices from our third party source and literature from Medical Cables, Inc. regarding their new ultrasonic transducers compatible with your fetal monitors.

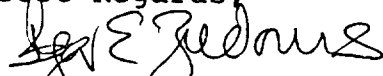
From our quick initial review of their new 115 compatible ultrasonic transducer here's some of what we found:

- 1.) An original (looks used) Corometrics transducer cover
- 2.) An original Corometrics connector
- 3.) An original Corometrics cable
- 4.) An original Corometrics internal metal plate
- 5.) PC board manufactured by MCI
- 6.) Poor workmanship inside housing; excess flux, solder, etc.

Unless MCI is buying these parts from you, they're using old used parts and selling them as new. This is fraud.

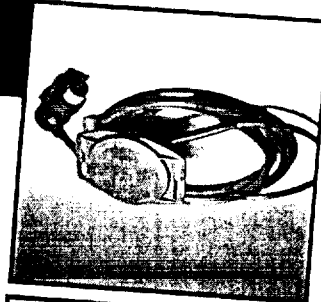
If you would like to see this transducer first hand, please let me know and I would be happy to meet with you. I appreciate your interest in this matter and don't hesitate to call me if you need more information.

Best Regards,


Igor E. Ziedonis
Vice President, Marketing

IEZ:nd

COMPARE OUR SERVICE



MEDICAL CABLES INC.
1308 LOGAN AVE. SUITE F
COSTA MESA, CA. 92626

Turn your broken **ULTRASOUND TRANSDUCERS**, **TOCO TRANSDUCERS**, and **LEG PLATES** into reconditioned or repaired units at a savings of up to 55% of replacement cost. You'll like our fast turn around time, top quality service, and six month warranty on all our repairs.
We also pay top dollar for all **COROMETRICS** and **HEWLETT-PACKARD** cables, regardless of condition, so ship those broken or unused cables today.

NEW ULTRASOUND TRANSDUCERS \$315.00
Compatible with COROMETRICS Model 111,112,115

CRITIKON DINAMAP BLOOD PRESSURE
Models 845,845 XT,847,1847,1847 XT

HOLTER RECORDERS (Plus Parts)

INFUSION PUMPS & CONTROLLERS

REPAIR ♦ CALIBRATION

\$250.00 / \$150.00

\$100.00

\$95.00 / \$50.00

*you
can see
two
transducers.
I still
have
it.*

MEDICAL CABLES INC.

1308 F LOGAN AVE.

COSTA MESA, CA 92626

(714) 545-3488

INVOICE

INVOICE NO: 2555

INVOICE DATE: 3-30-90

PAGE: 1

SHIPPED
TO

SHIP VIA: UPS
SHIP DATE: 3-30-90
DUE DATE: ASAP
TERMS: 5% NET 10

CUSTOMER ID:
P.O. NUMBER: 003293
P.O. DATE: 3-30-90
SALESMAN: PJB

ITEM	ORDERED	SHIPPED	DESCRIPTION	PRICE	AMOUNT
1	1	1	CORO US #115		259.00
				FTG.	13.50
				TOTAL	272.50

FOR RESALE

MAI MEDICAL
ACCESSORIES,
INCORPORATED

92 Youngs Road
Trenton, New Jersey 08619
(609) 890-8304
FAX (609) 890-0638

December 19, 1996

SENT VIA FAX TRANSMISSION AND REGULAR MAIL

Ms. Jean Kelahan
Investigator
U.S. FDA
120 N. Center Drive
North Brunswick, NJ 08902

Dear Ms. Kelahan,


It was a pleasure speaking with you recently. I hope your last visit to Medical Accessories, Inc. was successful.

I just wanted to pass along to you the most recent advertisement sent to hospitals nationally by Epic Medical (Exhibit A). The disturbing issue here is the continuation of false and misleading information. They state again, "All of our repairs utilize new parts only, and never use scavenged parts as part of the repair." Why then is it that just this past December 17, 1996 we mailed them back transducers we repaired for them. Repairs that did include brand new parts. Enclosed (Exhibit B-1 and B-2) you'll find their Purchase Order to MAI and our invoice back to them for repairing fetal monitoring transducers. There were also two more P.O.s sent that day.

If they have as they claim, new parts for every repair, why are they sending repairs to us? The disturbing issue here is they are getting away with false advertising to unknowing hospitals. Their ads make it seem Epic is doing exactly what MAI does, repairing every transducer with new parts. But, Epic is lying. I have transducers they've repaired which were sent to us direct from unhappy hospitals. We've torn them apart and have found used, scavenged parts. The same parts they're advertising they don't use.

I hope this information is of interest to you. The third party medical repair business is in dire need of being cleaned up. Please call me if I can be of any further assistance.

Sincerely,


Igor E. Ziedonis
President

cc: Janis G. Ziedonis, CEO

Specializing in Fetal Monitoring Products

COPY

EPIC MEDICAL ACCESSORIES, INC.

92 YOUNGS ROAD
TRENTON, NJ 08619
TEL (609) 890-8304 FAX (609) 890-0638

EXHIBIT B-2

EPIC MEDICAL EQUIP SERVICES
4643 WESTGROVE
DALLAS, TX 75248
ACCOUNTS PAYABLE

S
H
I
P
T
O

EPIC MEDICAL EQUIP SERVICES
4643 WESTGROVE
RECEIVING
DALLAS, TX 75248
P.O.# 1100052

PAGE NO. 1	INVOICE N 57627	APPLY TO	INVOICE DATE 12/16/96	CUST. NO. EP010
INVOICE			WORK ORDER NO.	B.O.

DATE SHIPPED		PURCHASE ORDER NO.		SHIP VIA		F.O.B.		TERMS	
12/16/96		1100052		UPS AIR		TRENTON		C.O.D.	
DATE REQUESTED		LOCATION		SALESPERSON		TERRITORY			
12/16/96		NJ				TEXAS			
ITEM NO.		DESCRIPTION		ORDERED	QUANTITY BACK ORD.	SHIPPED	UNIT PRICE	EXTENSION	TAX
T8040TOCOR		REPAIR HP TOCOTRANSDUCER 8040A, REPLACED CABLE, HOUSING BASE, POTS,	1		1		156.00	156.00	
T115TOCOR		REPAIRED COROMETRICS 115 TOCOTRANSDUCER 2260AAX, REPLACED CABLE, HOUSING, POTS REWIRED & RECALIBRATED TOCO	1		1		132.00	132.00	
12									
T116TRSR		REPAIRED COROMETRICS 116 ULTRA. TRANSDUCE REWIRED. WARRANTY	1		1				
ITEM KEY		SERIAL/LOT NO.		QUANTITY					
T8040TOCOR		HC8680, CT7140, CS1454		3					
SUB TOTAL							FREIGHT		291.
288.00							3.75		
THANK YOU FOR YOUR PATRONAGE							INVOICE NO. 57627		PLEASE REMIT THIS AMOUNT

CUSTOMER COPY



Epic Medical Equipment Services, Inc.
 4643 WESTGROVE DRIVE, DALLAS, TEXAS 75248
 (800) 327-3742 (972) 713-0444 FAX (972) 713-0465
 e-mail epic@computeek.net

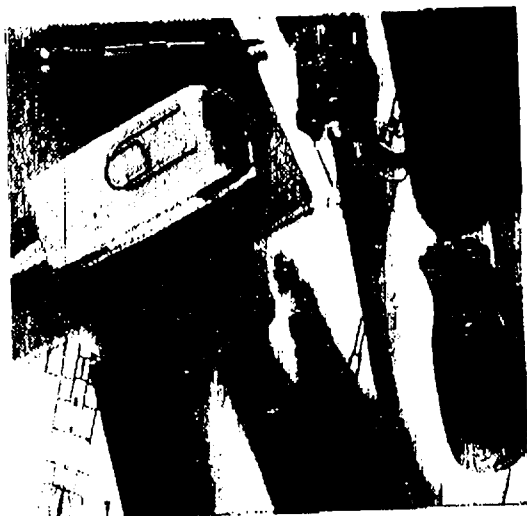
Maintenance

FIRST CLASS MAIL.
 U.S. POSTAGE
PAID
 PLANO, TX
 PERMIT NO. 87

1196

ATTN: BIOMEDICAL/CLINICAL ENGINEERING DEPARTMENT
 Mercer Medical Center
 PO Box 1658
 Trenton NJ 08607

08607-1658



Epic Medical Equipment Services, Inc.

INNOVATION AND CREATIVITY

EPIC developed the technology to repair the Pulse Oximeter Sensor in 1989 and was the first to repair the sensors that the manufacturers said could not be repaired. Since that time we have repaired thousands, enabling the hospital to gain significant savings.

We have added other new services to our repair line, including:

- Fetal Monitoring Transducers Oximeters
- Printed Circuit Boards used in Oximeters and IV Pumps

All of our repairs utilize new parts only, and never use scavenged parts as part of the repair.

Another QUALITY service from

EDIC

MAI MEDICAL
ACCESSORIES,
INCORPORATED

92 Youngs Road
Trenton, New Jersey 08619
(609) 890-8304
FAX (609) 890-0638

August 2, 1994

COPY

Director of Registration
Food and Drug Administration
Center for Devices and Radiological Health Devices
Registration and Listing Branch (HFZ-342R)
1390 Pickard Drive
Rockville, MD 20850-4332

Dear Director,

I know that funds have been cut and the FDA is short on investigators, but my concern is that the FDA sends two investigators to a small company like ours, under 20 people, for three days while other companies do not even register with the FDA and therefore avoid inspections and compliance with all FDA regulations. We have been registered with the FDA since 1976.

Most of these companies you do not inspect repair medical equipment with used parts (we have proof), mislabel products, switch labels and undercut honest companies that have been working and complying with the FDA and Good Manufacturing Practices since 1976.

As we have not found any evidence these companies are registered, if we may suggest it, the FDA might want to inform these companies that they must be registered with you. The companies we are specifically aware of and could not find any FDA registration are:

- | | |
|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| 1.) Medical Cables, Inc.
1340 Logan Ave
Costa Mesa, CA 92626
(800)828-1599 | 2.) Medelco
600 Industrial Way
Boynton Beach, FL 33426
(407) 547-0968 |
| 3.) SMC (Run by daughter of 1.)
no address (See enclosed
Advertisement)
(800) 336-5268 | 4.) Epic Medical Equipment
17618 Davenport, Suite #2
Dallas, TX 75252
(214) 713-0444 |
| 5.) Tri-Star
1104 Summit Avnue, Suite 101
Plano, TX 75074
(800) 578-3428 | 6.) Bio-Medical Equipment
2122 Palatka Road
Louisville, KY 40214
(800) 626-4515 |

Specializing in Fetal Monitoring Products

MAI MEDICAL
ACCESSORIES,
INCORPORATED

92 Youngs Road
Trenton, New Jersey 08619

(609) 890-8304

FAX (609) 890-0638

Food and Drug Administration

August 1, 1994

Page 2

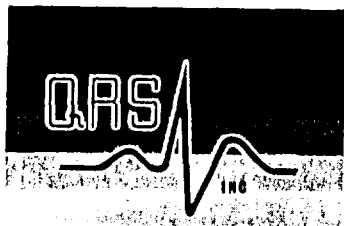
As I understand it, the function of government and its agencies is to protect the public and keep the marketplace fair and honest to all participants. If you are not in fact inspecting the companies I've listed, these companies not only have an unfair cost and regulatory advantage, but might be putting the public at risk who use their products and services.

The entire third party medical service industry needs to be investigated the same way you review Medical Accessories, Inc. operations. There are many companies unfairly and fraudulently repairing and selling equipment that borders on fraud. An example; advertising and selling used equipment as new.

I look forward to hearing from you regarding this matter.
Thanking you in advance.

Sincerely,


Igor E. Ziedonis
President



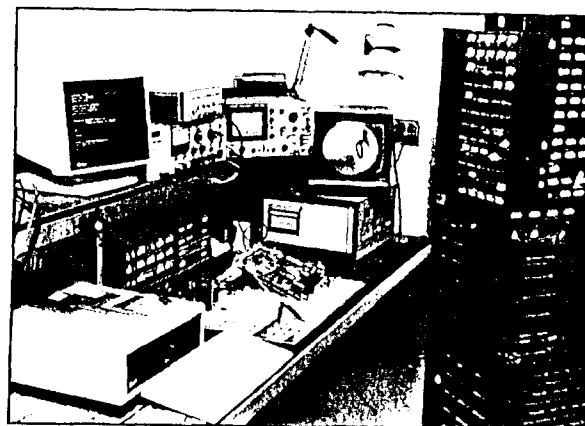
QRS MEDICAL SERVICES, INC. . . . Maintaining Your Image With SERVICE SUPPORT FOR OEC - DIASONICS C - ARMS

- ALL MODELS
- PARTS
- DEPOT REPAIR SERVICES
- TRAINING

Please Call Toll Free For Further Information

800-922-0056


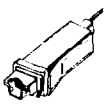

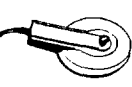


QRS MEDICAL SERVICES, INC.
1325 Route 130 South, Gloucester City, NJ 08030-2247
609/456-5055 • 609-456-8510 (FAX)



READER SERVICE NO. 7

SMC Can't Be Beat!

We Save You Time & Money Above All Competitors
Superior Quality, Sensible Pricing & Guaranteed Repairs On..

Pulse Oximeter Pre-Amp or Finger Probe Repair   \$ 145⁰⁰ <small>Neelcor, Space Labs, Ohmeda, CSI, Novametrics, Physio-Control, Datascope</small>	Alcon Phaco Ultrasonic Handpieces Repair <div> Refurbished \$ 1,595 </div>  <div> Repaired \$ 495 </div> <small>Includes Model Numbers 10000 & 9001 We Also Repair Site, Amo, Storz & Chiron Handpieces- Call for Estimate</small>
Fetal Monitoring Transducer Cable Repair   \$ 165^{00*} <small>Corometrics, Hewlett Packard, Litton</small>	Cast Cutter Repair <i>New Item!</i>  \$ 100⁰⁰ Plus Parts
Hand-held Doppler Ultrasound Repair	<small>Medasonics, Ultrascopes, Imex, Sonicaid, Hadeco, Etc</small> \$ 175⁰⁰

VOLUME DISCOUNTS AVAILABLE!! *PRICE INCLUDES ALL PARTS & LABOR (IF REPAIRABLE)
 6 Month Warranty on Cables 3 Month Warranty On Doppler U.S. 30 Day Warranty On Phaco Ultrasonic Repairs
 90 Day Warranty On Refurbished Phaco Ultrasonic Handpieces Most Repairs 48 Hr. Turnaround

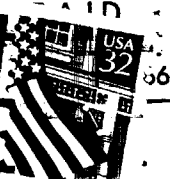
SMC (800) 336-5268

READER SERVICE NO. 8

MAI

MEDICAL
ACCESSORIES,
INCORPORATED

92 Youngs Road
Trenton, NJ 08619



BULK RATE
U.S. POSTAGE

Dockets Management Branch (HFA-305)
FDA
12420 Parklawn Drive
Room 1-23
Rockville, MD 20857